

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation and comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

#### Protocol summary

##### Study aim

Comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 186 patients. For randomization, three cards with letters A, B and C are placed in front of the patient and the patient selects one. Each letter belongs to one of three groups used

##### Settings and conduct

Sealed coded packages are provided to the resident and design partner to provide the drug to the patient based on the code and provide the necessary explanations to the mothers.

##### Participants/Inclusion and exclusion criteria

Admission criteria: Age 1 to 5 years with acute watery diarrhea. Exclusion criteria: fever above 38.5; severe dehydration; severe diarrhea; severe malnutrition; recent use of antibiotics or antidiarrheal drug; having another complaint in addition to watery diarrhea with immunodeficiency.

##### Intervention groups

Intervention group 1: The group under one year of age should take 5 drops of paddy lactate 5 drops every 8 hours and 1 to 2 years of Kidi Lactate powder 1/2 cup every 12 hours and over 2 years 1 pint every 12 hours. Intervention group 2: Vitamin D3 supplement group in the form of 800 units of 20 mg daily can be placed under two years due to 400 units of vitamin D drops in 400 units and over 2 years of dose 800 units of vitamin D3 to this group. 7 days control: This group is only allowed as a control group

##### Main outcome variables

Stool consistency; number of stools; duration of diarrhea; fever, anorexia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210615051584N1**

Registration date: **2021-07-04, 1400/04/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-07-04, 1400/04/13**

Update count: **0**

##### Registration date

2021-07-04, 1400/04/13

##### Registrant information

##### Name

Manige Ahmadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3222 0016

##### Email address

ahmadi.ma@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-06-17, 1400/03/27

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation and comparison of the effect of oral vitamin D and probiotics on acute non-inflammatory diarrhea in children 6 months to 6 years

#### Public title

The effect of probiotics and vitamin D on diarrhea in children

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Acute acute watery diarrhea

##### Exclusion criteria:

Fever above 38.5 degree Centigrade Severe dehydration Severe diarrhea Severe malnutrition Recent use of antibiotics or antidiarrheal drug Having another complaint in addition to watery diarrhea with immunodeficiency

#### Age

From **6 months** old to **6 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **186**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Three cards with the letters A, B and C are placed in front of the patient and the patient chooses one. Each letter belongs to one of three groups.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The patient and the evaluating physician are unaware of the study groups

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

##### Street address

Shahrekord University of Medical Sciences, Kashani St.

#### City

Shahrekord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

8818863472

#### Approval date

2020-06-30, 1399/04/10

#### Ethics committee reference number

IR.SKUMS.REC.1399.102

## Health conditions studied

### 1

#### Description of health condition studied

Acute watery diarrhea

#### ICD-10 code

A09.9

#### ICD-10 code description

Gastroenteritis and colitis of unspecified origin

## Primary outcomes

### 1

#### Description

Number of times diarrhea

#### Timepoint

Daily to 7 Day

#### Method of measurement

Question from the sick mother

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: the group under one year of age should take 5 drops of paddy lactate 5 drops every 8 hours and 1 to 2 years of Kidi Lactate powder 1/2 cup every 12 hours and over 2 years 1 pint every 12 hours. Intervention group 2: Vitamin D3 supplement group in the form of drops of 800 units of 20 mg daily can be under two years due to 400 units of vitamin D drops in the case of 400 units and over 2 years of 800 units of oral vitamin D3 for 7 days

#### Category

Treatment - Drugs

### 2

#### Description

Control group: this group receives only placebo as a control group for 7 days

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Hajar Hospital, Shahrekord

**Full name of responsible person**

Dr. Ali Asghar Rabiee

**Street address**

Hajar Hospital Nurse Street

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

a.rabiei@skums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Mehraban Sadeghi

**Street address**

Kashani St. Shahrekord University of Medical Sciences

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

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**Phone**

+98 38 3334 2414

**Email**

mehr.sadeghi1ir@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahre-kord University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Manigeh Ahmadi

**Position**

Associate

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Nurse Street

**City**

شهرکرد

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

ahmadi.ma@skums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Aliasghar Rabiee

**Position**

Consultant

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Hajar Hospital Nurse Street

**City**

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**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

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**Phone**

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**Email**

a.rabiei@skums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Manigeh Ahmadi

**Position**

Associate

**Latest degree**

Specialist

**Other areas of specialty/work**

Pediatrics

**Street address**

Hajar Hospital Nurse Street

**City**

Shahrekord

**Province**

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**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

ahmadimanijeh@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Some of the forgotten theory is related to the main message that can be divided.

**When the data will become available and for how long**

Access period starts 6 months after the results are published

**To whom data/document is available**

Only for researchers working in academic institutions

**Under which criteria data/document could be used**

Researchers who are writing meta-analysis articles

**From where data/document is obtainable**

Email address

**What processes are involved for a request to access data/document**

After sending the email via academic email and the reason for the need for data, this study will be provided to the researcher within a week.

**Comments**